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10/725,632

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EXAMINER

LEWIS, KIM M

ART UNIT

PAPER NUMBER

3772

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

NT

Office Action Summary

Application No.

10/725,632

Applicant(s)

SIGURJONSSON ET AL.

Examiner

Kim M. Lewis

Art Unit

3772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 6-20 is/are rejected.
- 7) ☒ Claim(s) 5 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input checked="" type="checkbox"/> Other: <u>Detailed Action</u> . |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :12/3/03,7/29/04, 8/13/04,2/2/05.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed 12/3/03, 7/29/04, 8/13/04 and 2/2/05 have been received and made of record. Note the acknowledged PTO-1449 enclosed herewith.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: : "w" is missing from Fig. 2, note page 8, lines 15-17. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: "86" located in Fig. 12 is not in the specification. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the

reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

4. The disclosure is objected to because of the following informalities:

Fig. 12, which represents a facing layer, is not described in the detailed description of specification;

In Figs. 25-28, projection elements appear to be indicated by reference character "57" not "56" as recited in the specification on page 34, lines 20-30 and page 35, line 4;

Page 29, line 19, "43" should read --47--;

Page 31, line 20, "43" should read --47--; and Page 32, line 28, "the needles" should read --the projection elements-- since they were previously defined as such.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 13 and 15-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a wound dressing for covering a region of skin, the wound dressing comprising a "facing layer comprising at least on discrete layer of cross-linked silicone gel having at least one aperture" or a wound dressing for covering a region of skin, the wound dressing comprising "a skin adherent facing layer of a discrete layer of cross-linked silicone gel having a plurality of preformed apertures arranged in a pattern", does not reasonably provide enablement for the wound dressing "consisting of facing layer comprising at least on discrete layer of cross-linked silicone gel having at least one aperture" or the wound dressing "consisting of a skin adherent facing layer of a discrete layer of cross-linked silicone gel having a plurality of preformed apertures arranged in a pattern". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. No where in the specification does the applicant state that the wound dressing "***consists*** of a facing layer ..." (emphasis added by the examiner). In fact, the methods of making the facing layer include partially curing the silicone gel until it is placed on the absorbent core and subsequently continuing the curing process in order to adhere the facing layer to the absorbent core.

With respect to claim 13, the applicant does not disclose a wound dressing having a partially cured silicone gel layer. Rather, applicant discloses in the method of making the dressing, partially curing the silicone gel such that when placed onto the absorbent core, the silicone gel layer can be fully cured to allow the silicone to adhere to the absorbent core. No where in the specification does applicant suggest the use of a final product of a partially cured silicone gel layer as a wound dressing.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 4, and 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,207,875 ("Lindqvist et al.").

As regards claim 1, Lindqvist et al. disclose a wound dressing that anticipates applicant's presently claimed invention. More specifically, Lindqvist et al. discloses a wound dressing (7) for covering a wound, comprising a skin adherent facing layer (3') consisting of a discrete layer of silicone gel (col. 3, lines 19-20 and col. 4, lines 51-52) having a plurality of preformed apertures (6) arranged in a pattern (note Figs. 2 and 2A).

Regarding claim 2, as can be seen from Fig. 2, Lindqvist et al. the silicone gel layer as being substantially planar along a proximal surface thereof.

Regarding claim 6, as can be seen from Figs. 2 and 2A, Lindqvist et al. disclose apertures that are generally circular.

As regards claim 7, Lindqvist et al. disclose the wound dressing according to claim 1, wherein the apertures are generally uniform in shape since the aperture of the foam are uniform in shape and the apertures of the gel takes on the same shape (note col. 6, lines 31-33).

Regarding claim 8, as can be seen from Fig. 2, Lindqvist et al. disclose apertures that are generally equally spaced from one another.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 2, 3, 9-11 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindqvist et al.

As regards claim 2, 3 and 9-11, Lindqvist et al. substantially disclose the invention as claimed except that the plurality of apertures are defined in a pattern varying in number per unit area according to their location relative to a center axis of the silicone gel layer, that the plurality of apertures are defined in a pattern varying in size according to their location relative to a center axis of the silicone gel layer, that the pattern of the apertures comprises alternating apertures of at least two different sizes, that the apertures have two different sizes, the first size being larger than the second size and the apertures of the first size being bordered by the apertures of the second size, and that the apertures of the second size are bordered by the apertures of the first size.

Lindqvist et al., however, disclose at col. 4, line 67-col. 5, line 5, that the absorption rate of the dressing can be varied by varying the density of the hole pattern and the size of the holes, and that the hole pattern increases the flexibility of the dressing. Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to vary the arrangement of the holes and size of the holes in the absorbent foam, thereby varying the arrangement and size of the holes in the gel, in order to achieve a desired effect (*e.g.*, increase the absorption rate, increase flexibility, *etc.*).

As regards claim 14, Lindqvist et al. inherently disclose the wound dressing according to claim 1, wherein the silicone gel layer has regions of varying thickness since the open cells are not uniform across the foam.

12. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lindqvist et al. in view of U.S. Patent No. 6,461,467 ("Blatchford et al.").

As regards claim 12, Lindqvist et al. fail to teach the silicone gel layer has a progressive increase of tackiness extending from a central portion to a border portion

Blatchford et al., however, disclose a medical dressing with two adhesives, wherein one adhesive has greater adhesive tack than the other so as to allow the dressing to adhere better to the skin at certain locations, for example, the periphery of the dressing, and adheres less to the portion which contacts the wound (abstract, col. 2, lines 12-20 and lines 31-38).

In view of Blatchford et al., it would have been obvious to one having ordinary skill in the art to provide the dressing of Lindqvist et al. with a silicone gel layer having two different tacks, in order to allow the center portion of the dressing which contacts the wound to adhere less than, for example, the periphery of the dressing to which surrounds the wound. This will allow the dressing to firmly adhere to the skin; but only at areas surrounding the wound.

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

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1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 and 14 of copending Application No. 10/725,575 (the '575 application"). Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 of the instant application is broader in scope. Claims 1 and 14 of the '575 application anticipate the subject matter of claim 1 of the instant application in that a skin adherent facing layer consisting of a discrete layer of silicone gel having a plurality of preformed apertures arranged in a pattern is covered by a perforated skin adherent facing layer secured to the proximal surface of the absorbent core (claim 1 of the '575 application) and wherein the facing layer is a discrete layer of silicone gel (claim 14 of the '575 application).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 27 of copending Application No. 10/725,561 ("the '561 application") in view of Lindqvist.

As regards claim 1, claim 27 of the '561 application substantially discloses applicant's invention. More specifically, claim 27 recites "a facing layer consisting of a

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discrete skin adherent, elastomeric gel,,said elastomeric gel layer having a plurality of through extending apertures provided in a pattern", thereby providing patentable coverage for a skin adherent facing layer consisting of a discrete layer of gel having a plurality of preformed apertures arranged in a pattern. Claim 27 is silent as to the type of elastomeric gel.

Lindqvist et al. disclose the use of a skin adherent silicone gel in a wound dressing. Lindqvist et al. teach the use of silicone gels, as well as other hydrophobic polyurethane gels as a matter of design choice. Absent a critical teaching, it would have been obvious to one having ordinary skill in the art to manufacture the dressing of claim 27 of the '561 application with a silicone gel, since they are well known and used in the wound dressing art.

This is a provisional obviousness-type double patenting rejection.

Allowable Subject Matter

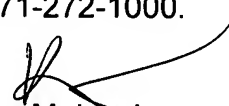
16. Claim 5 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim M. Lewis whose telephone number is (571) 272-

4796. The examiner can normally be reached on Monday to Friday, from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco, can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Kim M. Lewis
Primary Examiner
Art Unit 3772

kml
December 22, 2006